



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

ROSE et al.

Serial No.: 10/775,575

Filed: February 9, 2004

Atty. File No.: 4018-1-CON-2

For: "PRODUCT AND METHOD FOR
TREATING JOINT DISORDERS IN
VERTEBRATES"

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Dear Sir:

I, Rebecca J. Rose, declare as follows:

1. I am one of the named inventors on U.S. Patent Application Serial No. 10/775,575 entitled "Product and Method for Treating Joint Disorders in Vertebrates." I am also a named inventor on the following U.S. Patents: U.S. Patent No. 5,916,565; 6,344,220 and 6,709,682 having the same title.

2. In view of my educational and work experience, I believe that I am one of ordinary skill in the relevant art as it pertains to the present invention.

3. I am presently the President/CEO of In Clover, Inc., a company directed to the development of products for the treatment of joint disorders in vertebrates. I was formerly the Vice President of Gynelogix, Inc., a company specializing in the development of products relating to microbicides for women's health care. From 1994 through 1996, I was Director of Marketing for Chrisope Technologies, Inc. and was responsible for direct market expansion and strategic focus for clinical and industrial diagnostic products. From 1993 - 1994, I was business/technical development

) Group Art Unit: 1654
)
) Examiner: Susan D. Coe
)
) DECLARATION OR REBECCA J. ROSE
) UNDER 37 C.F.R. §1.131
)

) "EXPRESS MAIL" MAILING LABEL NUMBER: EV 331288112 US
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) VIRGINIA 22313-1450.

TYPED OR PRINTED NAME: Brenda Carpenter
SIGNATURE: Brenda Carpenter

manager for Harris Chemical Company and implemented new value added market strategies for company acquisitions and mergers. From 1990 - 1993, I was technical product development manager at ZeaGen (formerly Coors BioTech) and directed cross-functional teams in development, manufacture, regulatory fares and sales resulting in commercialization of biotechnology-based product lines. From 1987 - 1990, I was Laboratory Supervisor at ZeaGen and established and executed laboratory and operation protocol for scale-up from bench scale to 300,000 liter fermentation commercial processes. From 1985 - 1987, I was a fermentation microbiologist at Coors Biotechnology Company where I transferred fermentation processes from research to plant scale. From 1984 - 1985, I was Quality Assurance/Special Assignment Director at Coors Biotechnology and developed various microbial test procedures.

4. I received a Masters of Business Administration from the University of Denver, Denver, Colorado in 1992. In 1984, I graduated from the University of Northern Colorado with a Bachelor of Arts in Medical Technology and Microbiology.

5. The following statements are made with reference to the level of ordinary skill in the art at the time of the priority date of the above-referenced patent application, March 7, 1997.

6. I have reviewed the Office Action dated March 7, 2005 and references cited by the Examiner in the present case. In particular, I have reviewed the Hirschhorn, Hobbs, Castleman references and the '703 and '845 patents relied upon by the Examiner to reject claims on the basis of obviousness.

7. With respect to the Examiner's arguments that several of the pending claims are rendered obvious by a combination of the above references, I, as one of ordinary skill in the art, declare that one of ordinary skill in the art, at the time of the present invention, would not have made the combination the Examiner proposes. Moreover, even if, *arguendo*, such combination were

made, one of ordinary skill in the art would not believe that the combination of such references would render the present invention, as embodied by the pending claims, obvious to one of ordinary skill in the art at the time of the present invention. I concur with the arguments presented in the Amendment and Response accompanying this Declaration and such arguments form the basis for my opinion and are incorporated herein.

8. The Examiner contends that it would have been obvious to combine the particular ingredients as set forth in the claims because such a combination “flows logically from their having been used individually in the prior art.” The Examiner concludes that an artisan of ordinary skill would have had a reasonable expectation that a combination of the particular substances combined in the claims would be useful in creating an arthritis treating composition, and apparently, based upon such alleged “reasonable expectation”, the artisan would have been provided with the motivation to make such a composition. I respectfully disagree. None of the cited references provide the motivation to combine prior art teachings in a manner so that one of skill in the art would have arrived at the claimed invention. As established by the accompanying testimonials, the Examiner is also mistaken with respect to a factual predicate: the effects of the Connectin product cannot properly be considered to be “no more than the additive effect of the ingredients.”

9. Although the Examiner admits that the references “do not specifically teach adding the ingredients in the amounts claimed by applicant”, the Examiner nevertheless contends that optimization of such amounts would allegedly have been obvious to a person of ordinary skill in the art “in order to best achieve the desired results.” While I disagree with the Examiner’s contention that one of ordinary skill in the art at the time of the present invention would have simply “optimized” the amount of each particular ingredient in the claimed combination in order to achieve

desired results, the testimonials from actual users of the Connectin product demonstrate “unexpected results” and show the nonobviousness of the claimed invention.

10. The testimonials attached hereto as Exhibit A are true and accurate representations of communications I have received from the particular individuals whose names are listed below such testimonials. I believe that in addition to the technical differences that exist between the claimed invention and the cited references, the significant response from users of the product and the interest shown by commercial entities in selling the product, there is little question that the claimed invention is not obvious.

11. In further support of the patentability of the present invention, the Examiner should be aware that the sales of the claimed invention under the trademark “Connectin®” has generated sales of approximately \$3,318,100 with over 6 million servings of Connectin ® having been sold. Moreover, In Clover is presently under confidential disclosure agreements and is in discussions with two companies concerning business arrangements concerning the Connectin® product. One company is a well known global pharmaceutical company and the other is a U.S. company with over 50 years as one of the nation’s leaders in the animal health care industry. Such interest by commercial entities in the Connectin® product is another indicia of the non-obviousness of the present invention.

12. For the above reasons, I submit that the present invention, as claimed, would not have been obvious to one of ordinary skill in the art at the time of the present invention.

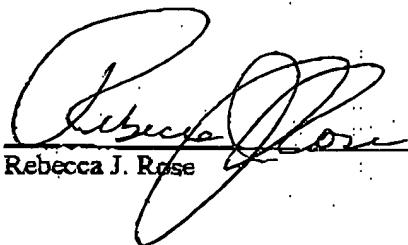
13. I declare that all statements made herein are of my own knowledge, are true, and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful, false statements and the like so made are

punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or any patent issuing thereon.

14. Further declarant sayeth not.

7-07-05

Date


Rebecca J. Rose

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EXHIBIT A

"I just wanted to tell you how pleased I am with your Connectin product. I have an 8 1/2 year young German Shepherd named Elsa. We attained her Utility title and Schutzhund BH a few years ago and were forced to stop training and competing due to arthritis in her back and hips. I've always supplemented Elsa with glucosamine/chondroitin and other supplements as well. I saw your Cormectin product in the KV Vet catalog and was very impressed with the ingredients. I ordered it and within two weeks Elsa started acting about 5 years younger! Mind you that she was on another supplement but the real improvement came when I put her on the Connectin. As a matter of fact, I didn't tell anyone she was on a new supplement and people started asking me "What in the world has gotten into Elsa???" Connectin has gotten into her and I am grateful for the quality of life it has given her. She is truly worth it."

Thank you,

- T. R., Felton, Delaware (September, 2004)

"It was a holiday weekend and Bud cried when climbing stairs and getting up. After seeing the vet and getting a prescription for a pain reliever, Stanley (my other dog) and I went to Elmwood Pet Supply in Buffalo, NY. The owner took us directly to the Connectin. One customer commented that Connectin added many happy years to her dog's life. Another customer also told me how his dog was having a hard time walking, and after using Connectin ran like a puppy. The change in Bud was almost immediate. Bud was on the pain reliever for one week, and now only takes Connectin. He hops on the bed, into the car, and runs circles around Stanley in the yard"

- Anne Tryjankowski, West Seneca, New York (June, 2002)

"Our dog, Tucker, was failing to respond to veterinary medications for arthritis and age. We were afraid that his quality of life was diminishing. And then we discovered your product. He has been on the Connectin plan for about seven months now. From the expression on his face, you can tell that our 'pal' is feeling fine. At 11 years, he is slower than we remember, but from his morning smile to his late night kisses, Tucker is moving around with more agility. Thanks for a product that truly contributes to our pet's quality of life. We've rarely written to a manufacturer to commend their work. Our hats are off to you! Thank You"

- Michael Engle, Denver, Colorado

"Thank you so much for providing a natural alternative to pharmaceutical treatments to treat our dog's hip dysplasia. Flash Gordon (our yellow lab) started holding up his back leg only ten minutes into playtime at just over two years old. Since starting Connectin, Flash no longer shows symptoms and is back on the trails and at the dog park, playing fetch for hours. While Caruso (Black Lab) is not showing symptoms of hip dysplasia, our vet warned us that her hips show potential for the disease. We're taking no chances; both dogs are taking Connectin!"

- R&J S., Denver, Colorado (February, 2003)

“Last year Marie started showing signs of pain and discomfort when being petted, going up and down the stairs & getting in and out of the car. I purchased Connectin and was positively shocked to see Marie running and scampering like her old self in about a week! What blessing Connectin has been. Thanks for making such a great product it must be nice to know what you do makes a difference in someone else’s life.”

- Victor Keranen, Seattle, Washington (December, 2002)

“Our vet diagnosed Arthur with a joint disorder in his right hind knee. We saw results very quickly with Connectin. Arthur now begs to go on walks around the lake. We’re very happy that Connectin has allowed Arthur to continue to be active. He is a very important member of our family!”

- Dick Zimmer, Woodbury, Minnesota (January, 2001)

“Two months ago, Shasta was limping badly after an afternoon romp. We learned from our vet that a key ligament had torn on her knee, requiring surgery. We also learned that Shasta’s size causes unusual stress on her joints resulting in bone spurs on her elbows and the beginning signs of dysplasia. We’ve been using Connectin for a month now, are seeing some improvement in Shasta’s condition already and are pleased to say that Shasta loves Connectin! We’re confident that we’ve found the best product for Shasta and are delighted that she agrees!”

- Anita Bonacci and Rolf Mygaard, Littleton, Colorado (April, 2002)

‘I’m amazed at how Connectin chewable tablets really work! I started giving my 11 month old puppy Jell Connectin tablets in May and within 3 days, I saw improvement. I’d tried other joint supplements in the past, but without results. He runs and plays like he doesn’t have arthritis/hip dysplasia. Jett doesn’t cry anymore when he gets up from laying down or after a hard day’s activity. He’s happy and that’s what makes me happy.’

- Robin Johnson, Omaha, Nebraska (July, 2002)

“Our 9-year-old Mandie loves to run! It was heartbreaking to notice her tendency to limp and to read the pain in her big brown eyes. We were told that she had vulnerable little patellas and would most likely have limited use of her knees by age 4 or 5. We decided to take some early steps towards protecting her, so I was delighted to find Connectin with it’s formulation of healing herbs and glucosamine. It’s truly amazing how nimble she has remained. Our vet remarks constantly on how young she acts and how lively she still is. We feel so blessed to have the gift of Mandie’s dear companionship in our lives. Thanks to Connectin, we look forward to many more years of running, jumping and playing together.”

-B.T. (April, 2003 - via email)